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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------------|------------------|
| 10/070,758 | 03/12/2002 | Helmut Witteler | 50733 | 2769 |
| 26474 | 7590 | 02/13/2004 | | |
| KEIL & WEINKAUF 1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036 | | | EXAMINER FUBARA, BLESSING M | |
| | | | ART UNIT | PAPER NUMBER |

1615
DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,758

Applicant(s)

WITTELER ET AL.

Examiner

Blessing M. Fubara

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-- **Th MAILING DATE of this communication app ars on th cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of amendment and request for extension of time filed 11/03/03. Claims 1-9 and 12 are pending.

Claim Rejections - 35 USC § 112

1. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because claim 4 is amended to properly depend from claim 3.
2. The rejection of claims 10 and 11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is moot because claims 10 and 11 have been cancelled.

Claim Rejections - 35 USC § 103

3. The rejection of claims 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over Denzinger et al. (US 4,402,937) in view of Shetty (US 4,113,857) is moot because claims 10 and 11 have been cancelled.

Claim Rejections - 35 USC § 102

4. Claims 1-9 and 12 remain rejected under 35 U.S.C. 102(b) as being anticipated by Denzinger et al. (US 4,402,937).

The Rejection:

Denzinger discloses a process for preparing polyvinylpyrrolidone (PVP)-iodine by reacting the PVP with elemental iodine in the presence of formic acid, oxalic acid, or ammonium

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salt or amide of carbonic acid, formic acid or oxalic acid and the reaction is carried out in aqueous solution (abstract and column 3, lines 1 and 2). The preparation starts with an aqueous solution of PVP of from 10-60% (column 4, lines 33-37), the PVP has a K value of from 8-50 (column 3, lines 37-41). In example 1, iodine is in an amount of 6% based on the weight of PVP and an available amount of 4.1%. The available iodine in example 2 is 5.1% and 6.2% in example 3. The mixture of the PVP and iodine and formic acid is heated at 70 °C for 20 hours (example 1), at 80 °C for 5 hours (example 2) and at 75 °C for 2 hours and a solid product is isolated from the aqueous solution by drying, spray drying or spray granulation (column 4, lines 53-56). See also claims 1-3. Instant claim 12 is a composition claim and future intended use is not critical in a composition claim. Formic acid is a reducing agent of the instant claims. The examples are exemplifications illustrating some aspects of the disclosed process and do not cover all possible combinations of the range of the K-values of PVP-solutions and the concentration of the PVP-solutions. The teaching of Denzinger meets the limitations of the instant claims.

Applicants' Arguments and Response to Arguments:

1) The viscosity of aqueous PVP solution increases with increasing K values at a given concentration, and the viscosity of aqueous PVP solution increases with increasing concentration at given K value. One of ordinary skill in the art would employ a highly concentrated PVP solution only where the PVP has a low K value since the formation of PVP-iodine is slow and would therefore require low viscosity to ensure good intermixture as possible. At K value of 12.5 (preparatory method A) and 17 (preparatory method B), Denzinger adapts the concentration of the PVP to 50% and 40% respectfully. Applicants

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thus conclude that Denzinger fails to show that the concentration of PVP be adapted to meet the equation/formula $c > 100 \times [0.1 + 8/(K + 5)]$.

5. Applicants' arguments filed 11/03/03 have been fully considered but they are not persuasive. Applicants rely on viscosity at the beginning of the argument and this feature of applicants' invention upon which applicants rely is not recited in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Secondly, applicants' process is directed to mixing an aqueous solution of PVP and at least 4.0% elemental iodine and the requirement is that the PVP concentration obey the equation/formula $c > 100 \times [0.1 + 8/(K + 5)]$. Applicants claimed no specific concentration of the PVP solution in the generic claim but gives a range of K values, which the prior art discloses. Denzinger discloses a process of preparing PVP-iodine by mixing a 10-60% PVP solution (column 4, line 35) and the PVP employed generally has a K value of from 8-50 (column 3, line 38). Denzinger discloses that the mixing process involves heat step and use of reducing agents that are also claimed by applicants. The examples cited by applicants are exemplifications of aspects of the prior art that discloses K values in applicants claimed range and concentrations of PVP-solutions that are within the applicants PVP concentration claimed in the dependent claims and as noted by applicants; and it is respectfully noted that all variations of the disclosure of the prior art need not be exemplified.

2) The representative example 1 of Denzinger uses PVP prepared from example I of DAS 2,818,767 and in that example PVP has a concentration of 30% and a K value of 31.5; representative examples 2 and 5a to 5c of Denzinger uses PVP solution from

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example II of DAS 2,818,767 and in that example the concentration of PVP is 40% with a K value of 16.6. Examples 3 and 4 use the PVP prepared in examples A and B. On this basis applicants compiled the data in table on page 4 of the remarks filed 11/03/03.

6. Applicants' arguments filed 11/03/03 have been fully considered but they are not persuasive. Applicants refer to examples, which are exemplifications of aspects of the disclosure of the prior art. The prior art discloses a process where 10-60% PVP solution having a K value in the range 8-50 is mixed with iodine. Applicants claimed no specific concentration of PVP-solution that corresponds with specific K value. The table presented by applicants does not exclude other combinations that are possible from the prior art. Plugging the range of K-values into applicants' equations results in the concentrations in column 4 of the table provided by applicants in the remarks. Applicants failed to claim concentration of PVP-solution having a specified K-value and thus the table computed by applicants does not exclude Denzinger as prior art under 35 USC 102.

In summary, instant process claim 1 mixes aqueous PVP-solution and elemental iodine where the concentration of the PVP-solution obeys the equation/formula of claim 1 where the K-value is in the range of 10-100. The prior art discloses a process of preparing PVP-iodine by mixing 10-60% PVP-solution having K-value in the range of 8-50 in the presence of reducing agents and where a heat step is required. The prior art disclosure stating that higher concentrations apply to polymers of low K-values is a relative expression that does not categorically link a concentration to a K-value and one that does not categorically exclude all possible combinations within the range of concentrations and K-values of the PVP-solutions. Similarly, applicants failed to claim a K-value that is categorically linked with a specific

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concentration of any PVP-solution. Denzinger discloses the claimed process. US 4,200,710 was not cited as prior art. Lines 60-63, of column 2 of Denzinger disclose stable aqueous PVP-iodine solution prepared by the disclosed prior art process. Since the prior art discloses the instant process, the product formed by the process would necessarily avoid the issue of agglomeration. The prior art discloses a range of reaction time of 0.5 to 30 hours that falls within the reaction time claimed in the dependent claim 2 of 0.5 to 15 hours. Applicants' statement in the remarks that no agglomeration forms at applicants' reaction time of 4-11 hours includes the prior art reaction times of from 0.5 to 30 hours. Further, applicants' statement in the remarks that agglomeration occurs at reaction time of 21 hours does not overcome the prior art reaction time of 0.5 to 11 hours that is in the range of 0.5 to 30 hours. It is also respectfully noted that there is no data for reaction time of 11.1 to 20.9 hours.

The rejection is thus maintained.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

